
Please Direct All Correspondence to Customer Number 20,995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Jae Keol Rhee, <i>et al.</i>
App. No	:	10/596,412
Filed	:	June 13, 2006
For	:	NOVEL OXAZOLIDINONE DERIVATIVES
Examiner	:	Patricia L. Morris
Art Unit	:	1625
Conf No.	:	6355

**REQUEST FOR RECONSIDERATION OF THE DECISION ON APPLICATION FOR
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.181(a)(3)**

Mail Stop Petition

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants invoke the Supervisory Authority of the Director under 37 CFR § 1.181(a)(3) and Request Reconsideration of the Decision on Application for Patent Term Adjustment ("Decision") mailed September 14, 2010. No fee requirement is set forth in 37 CFR §1.181 and thus no petition fee accompanies this Request. However, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Applicants submit this Request in accordance with 37 C.F.R. § 1.181(a)(3), to bring errors in the Decision to the Office's attention. The Applicants respectfully request reconsideration to correct the Patent Term Adjustment (PTA) calculation of 254 days as indicated in the Decision, as of the mailing date of the Notice of Allowance, by the United States Patent and Trademark Office (hereinafter the "Office") to 864 days.

The discrepancy between these two time frames appears to hinge, at least in part, on the Office's unsupported finding that "Group Directors in Technology Centers have the authority to vacate Office actions. Examiners and Quality Assurance Specialists do not have the authority to vacate Office actions." See Decision, page 2. The Petitions Director erred in the Decision,

because the proffered finding was arbitrary or capricious and/or was not supported by substantial evidence. Assuming *arguendo* that this finding was supported by substantial evidence, the undisputed facts on the record show that the Quality Assurance Specialist did not vacate any Office Actions but rather merely clarified the Petition Decision at the express direction of Director Yucel in the Petition Decision. The Applicant's position set forth in the Request for Reconsideration of the Patent Term Adjustment falls squarely in line with the spirit of the rules, namely to provide an adjustment of term due to the Office's delay. The Statement of the Facts immediately following outlines the Office's gross delay in issuing a Notice of Allowance, to the Applicants' significant temporal (and financial) disadvantage.

Statement of the Facts

It is undisputed that the original Restriction Requirement dated October 8, 2008 was replete with errors, as was acknowledged in the Petition Decision decided on October 8, 2009 signed by Remy Yucel, Director, Technology Center 1600 (hereinafter "Director Yucel"):

in the first Office action on the merits, the examiner has, on one hand, withdrawn an independent claim 17 directed to a method of preparing an oxazolidinone derivative of Formula (I) while on the other hand, examined claims 18, 19 and 20m [sic] each of which directly depends upon and further limits the method of withdrawn claim 17. This is improper....

[T]he original lack of unity determination placed the process claims in Groups XII, XIII and XIV. In the supplemental non-final Office action mailed February 11, 2009, the restriction requirement between Groups XII, XIII XIV was withdrawn, such that the process claims which are pending on February 11, 2009 were examined together on the merits.

In view of these inconsistencies the Office has not established a clear record as required by and MPEP 814, which states:

The examiner must provide clear and detailed record of the restriction requirement to provide a clear demarcation between restricted invention so that it can be determined whether the inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double-patenting rejections under 35 U.S.C. 121. [Citations omitted.]

The claims as currently pending are now considered for unity of invention anew in this decision.

See Decision on Petition dated October 8, 2009 pages 3-5.

The original Restriction Requirement dated March 6, 2008, along with statements made in the subsequent Office Actions, contained numerous additional errors and inconsistencies,

which do not provide a clear demarcation between restricted inventions in accordance with MPEP § 814.¹

It is undisputed that the Applicants elected Group VIII (Group 8) in the response filed March 19, 2008. The Decision on Petition dated October 8, 2009, page 1, signed by Director Yucel, confirmed that such an election was made.

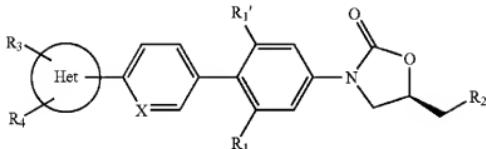
It is undisputed that the Examiner acknowledged Applicants' election of Group VIII (that is, Group 8), in the Office Action dated June 23, 2008, page 2; however, the Examiner inconsistently proceeded to examine Group XIII (that is, Group "13"), method Claims 18-20, and thus, the Examiner did not provide a clear demarcation between restricted inventions.²

It is undisputed that the Examiner issued 3 more consecutive Office Actions before the Applicants filed a response. The second, third, and fourth Office Actions are summarized below.

The Examiner issued a second Office Action dated December 16, 2008 in which the June 23, 2008 Office Action was vacated. The Examiner incoherently stated that method "Claim 21 [dependant upon method Claim 17] had been inadvertently included in Group VIII [where X is N and het is tetrazole in Formula I] but it is not drawn to the same halogenation reaction." Again, the Examiner did not provide a clear demarcation between restricted inventions. Further, the Examiner essentially repeated the rejections in the prior Office Action, and did not address the Group VIII composition of matter claims.

¹ For instance, Groups I-XI are inconsistently grouped. Specifically, Claim 1 was directed to a chemical genus having the following formula:

<Formula. 1>



wherein each variable in formula 1 was defined therein. This chemical genus was restricted into Groups I-XI, depending on whether X was C or N, and arbitrarily wherein het was one of the following 5 rings: pyrrole, furan, piperazine, tetrazole, or oxadiazole. However, Claim 1 defined "het" as selected from one of 17 different rings. Based on the same (albeit faulty) logic for restricting the original 10 groups, presumably, the Examiner could have included 24 additional groups wherein X was C or N in combination with each of the 12 remaining rings defined in Claim 1. However, the Examiner did not make such 24 additional groupings. Instead, the Examiner inconsistently indicated that Group XI included "any compounds not grouped in the above groups [I-X] because claim 1 is too vague to further group." The examiner did not indicate what was vague, or provide any reason why 24 additional groupings were not made.

² The Examiner also indicated a shortened statutory reply date of 1 month. This response deadline was later corrected and the timing reset according to an Interview Summary dated September 23, 2000.

The Examiner issued a third Office Action dated January 29, 2009 in which the following was stated: "Julie Burke, STRE has directed that the restriction requirement be rewritten to include claims 17, 21 and 22 with claims 18-20 based on an alleged conversation with the applicants." The Examiner rejected method Claims 17-22 under similar grounds that were applied against claims 18-20 in the prior two Office Actions.

The Examiner issued a fourth Office Action dated February 11, 2009 indicating that the January 29, 2009 Office Action was vacated. In this Office Action, Examiner stated that "the restriction requirement among groups XII- XIV set forth in the office action of March 6, 2008 is withdrawn." The Examiner rejected Claims 17-22 and 36-44 based on similar grounds found in the prior three Office Actions.

The Applicants submitted an Amendment dated May 11, 2009 deleting the original claims and adding: a) method claims directed to making the compound of Formula 1 (restricted to the Group VIII subject matter wherein X is N and het is tetrazole), b) related compound claims directed to Formula 1, c) related pharmaceutical claims, and d) related method of treatment claims. The Applicants argued against the rejections made in the February 11, 2009 Office Action and requested rejoinder of the withdrawn compound, composition, and method of use claims.

In the Office Action dated August 13, 2009 the Examiner a) issued a new Restriction Requirement with respect to claims 54-99, which was made final; b) rejected method claims 51-52 as obvious based on a similar obviousness rejection made in prior Office Action; and c) issued a new indefiniteness rejection.

Two weeks later on August 27, 2009, the Applicants responded to the Final Office Action dated August 13, 2009 arguing the impropriety of the new Restriction Requirement, obviousness rejection and the indefiniteness rejection.

An Advisory Action issued on September 4, 2009.

Ten days later on September 14, 2009, the Applicants filed a Request for Reconsideration of the Restriction Requirement and also a Pre-Appeal Brief Request for Review. Both were found in favor of the Applicants: the Petition was granted in full on October 8, 2009 and the Notice of Panel Decision from Pre-Appeal Brief Review dated October 22, 2009 indicated an "[a]llowable application." Julie Burke, Quality Assurance Specialist, along with the Examiner and her supervisor were on the panel.

It is undisputed that the eight-page Petition Decision decided on October 8, 2009 was signed by Director Yucel. It is undisputed that the Petition Decision summarized the prosecution history and indicated that, in addition to the Office Action dated June 23, 2008 and January 29, 2009, the Office Action mailed December 16, 2008 was vacated according to the Office Action dated January 29, 2009. Further the Petition Decision indicated that the Final Office Action mailed August 13, 2009 was also vacated. The Director acknowledged "the extensive delays in initiating prosecution on the merits in this application" (page 7). In addition, it is undisputed that

the Director stated "should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, in a letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512...."

On November 19, 2009, Applicants' counsel called Julie Burke by telephone, as directed by Director Yucel in accordance with the Petition Decision, to clarify the status of several actions in terms of potential Patent Term Adjustment. It is undisputed that an Interview Summary dated December 7, 2009 stated that the following actions were "vacated":

Restriction Requirement mailed 3/6/08;
Office Action mailed 6/23/08;
Office Action mailed 12/16/09;
Office Action mailed 1/29/09;
Supplemental Office Action mailed 2/11/09;
Final Office Action mailed 8/13/09; and
Advisory Action mailed 9/4/09 "[b]ecause all Office actions up to and including the final Office action have been vacated from the record."

In addition, the Interview Summary stated that the Notice of Appeal filed on 9/14/09 was considered untimely because the claims had not been rejected twice on the merits and a request for refund for the fees paid for filing the Notice of Appeal was encouraged.

Finally, the Interview Summary stated "[t]he Office regrets the delays and inconveniences which occurred during prosecution of this application and hopes this helps simplify the processing of Applicants PTA adjustments."

It is undisputed that the Applicants filed a Request for Refund dated December 7, 2009 based on the Office's suggestion.

It is also undisputed that the Office properly indicated in a Communication Re: Appeal dated November 20, 2009, and attached to the Interview Summary, that the Notice of Appeal filed September 14, 2009 was not timely filed.

It is further undisputed that the Office properly refunded the Notice of Appeal fee of \$540 on January 10, 2010.

It is also undisputed that the Office acted properly in refunding the Notice of Appeal fee of \$540 because, in accordance with statements made in the Interview Summary dated December 7, 2009, the claims have not been twice rejected twice on the merits, because all Office actions up to and including the final Office action were vacated.

Statement of the Law

It is unlawful for the Office's actions, findings, and conclusions to be "arbitrary" or "capricious," or unsupported by "substantial evidence" in accordance with the Administrative

Procedure Act (APA, 5 U. S. C. § 706³). The Supreme Court decided that § 706 applies to the Office's reasoning:

A reviewing court reviews an agency's reasoning to determine whether it is "arbitrary" or "capricious," or, if bound up with a record-based factual conclusion, to determine whether it is supported by "substantial evidence."

Dickinson v. Zurko, 527 U.S. 150, 164 (1999).

Analysis

As mentioned above, according to the Decision, the discrepancy between the Applicants' calculation of Patent Term Adjustment (864 days) and the Petitions Director's calculation (254 days) hinges, at least in part, on whether an Examiner and/or a Quality Assurance Specialist have authority to vacate Office Actions. Significantly, however, the undisputed facts on the record show that the Quality Assurance Specialist did not vacate any Office Actions but rather merely clarified the Petition Decision at the express direction of Director Yucel in the Petition Decision.

It is asserted herein that:

- a) the purpose of the Interview Summary was to "to clarify the status of several actions in terms of potential patent term adjustment" (rather than to vacate Office Actions);
- b) the Office has presented contradictory positions that the Office Actions were vacated and were not vacated;
- c) the Office has not established that the Examiner and the Quality Assurance Specialist have no authority to vacate Office Actions;
- d) the Office has not established that Director Yucel did not acquiesce to the statements made in the Petition Decision indicating that various Office Actions were vacated during prosecution;

³ Section 706 reads in relevant part as follows:

§ 706. Scope of Review
The reviewing court shall—
* * * * *

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
* * * * *

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute....

5 U.S.C. § 706(2)(A), (E) (1994).

- e) the Office has not established that only the Group Director has authority to vacate Office Actions; and
- f) the Office should vacate the Restriction Requirement mailed 3/6/08.

Each of these assertions is discussed below in detail.

- a) The purpose of the Interview Summary was to "to clarify the status of several actions in terms of potential patent term adjustment" (rather than to vacate Office Actions)

The Petitions Director erred by not establishing based on substantial evidence that Julie Burke, Quality Assurance Specialist, vacated Office Actions *on her own authority* in the Interview Summary dated December 7, 2009. It is undisputed that the Interview Summary dated December 7, 2009 stated that the nature of the interview was "to clarify the status of several actions in terms of potential patent term adjustment." Thus, based on the undisputed facts, the Interview Summary did not indicate any actions to be taken, but rather clarified the status of various applications in accordance with the Petition Decision. Specifically, the Interview Summary *clarified* that all Office Actions were vacated by the Petition Decision signed by Director Yucel.

Moreover, it is undisputed that Director Yucel stated "should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, in a letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512...." Thus, assuming *arguendo* that the Office shows by substantial evidence that Quality Assurance Specialists have no authority to vacate Office Actions, the undisputed factual record stated that Director Yucel delegated the authority to answer any clarifying questions about the Petition Decision to Quality Assurance Specialist Julie Burke. Thus, the issue of whether Quality Assurance Specialists have authority to vacate Office Actions is misplaced.

The Office has provided no evidence, and certainly no "substantial evidence," to suggest that a Quality Assurance Specialist, in contrast to Director Yucel in the Petition Decision, vacated the Office Actions enumerated in the Interview Summary. Thus, the reasoning set forth in the Petition Decision indicating that Quality Assurance Specialists have no authority to vacate Office Actions contradicts the undisputed facts that the statements made in the Interview Summary were specifically made to clarify the status of the Office Actions based on the Petition Decision. Thus, the Office's reasoning based on this finding is unlawful as arbitrary or capricious and/or unsupported by substantial evidence and must be set aside in accordance with the APA and the Supreme Courts' decision in Zurko.

In addition, the Office's reasoning was arbitrary or capricious because the Office previously acted on the record that the Office Actions were vacated, as discussed in the following section.

- b) The Office has presented contradictory positions that the Office Actions were vacated and were not vacated

In contrast to the Petitions Director's finding in the Decision that various Office Actions were not vacated (see page 2), the Office has indicated the contrary as discussed below.

It is undisputed that the Office properly indicated in a Communication Re: Appeal dated November 20, 2009, and attached to the Interview Summary, that the Notice of Appeal filed September 14, 2009 was not timely filed.

It is undisputed that the Applicants filed a Request for Refund dated December 7, 2009 and the Office properly refunded the Notice of Appeal fee of \$540 on January 10, 2010.

The Notice of Appeal was not timely filed because, in accordance with the clarifying statements made in the Interview Summary dated December 7, 2009, the claims have not been rejected twice on the merits, because all Office Actions up to and including the final Office Action were vacated. See Interview Summary dated December 7, 2009, continuation sheet.

In direct contrast, according to the Decision:

A Group Director only vacated one Office action in this case. Specifically, on October 8, 2009, the Office issued a decision signed by a Group Director vacating the Office action issued August 13, 2009.

See page 2.

However, the Office had previously indicated that the Office Actions properly were vacated based on the decision to refund the Notice of Appeal fee of \$540. An inconsistency would be introduced into the record if the Office Actions were not considered vacated because the claims arguably could have been twice rejected on the merits in accordance with any two of the three remaining allegedly non-vacated Office Actions; the Notice of Appeal arguably could have been filed properly. However, the Office has already acted on the status of the vacated Office Actions because the Office refunded the Notice of Appeal fee of \$540.

Thus, the Petitions Director's later finding that various Office Actions were not vacated is arbitrary or capricious in view of the Office's contradictory position in refunding fees based on the vacated status of the Office Actions. Thus, the Petitions Director's finding is unlawful and must be set aside in accordance with the APA and the Supreme Courts' decision in Zurko.

Moreover, the Office has provided no basis for its finding that "Quality Assurance Specialists do not have the authority to vacate Office actions."

- c) The Office has not established that the Examiner and the Quality Assurance Specialist have no authority to vacate Office Actions

The Decision states on page 2 that "Examiners and Quality Assurance Specialists do not have the authority to vacate Office actions." However, the Petitions Director has not pointed to the MPEP or one of its internal procedures and, therefore, has provided no evidence, and

certainly no "substantial evidence," to support this finding. The Applicants, after diligent research and review of the MPEP, have found no basis for this finding. Thus, the Applicants respectfully request that the Office provide basis for this finding. Otherwise, this finding is unlawful as lacking substantial evidence and must be set aside in accordance with the APA and the Supreme Courts' decision in Zurko.

Moreover, the Group Director's Petition Decision expressly stated that several Office Actions were vacated and the Decision provided no evidence that the Group Director did not acquiesce to these statements.

- d) The Office has not established Director Yucel did not acquiesce to the statements made in the Petition Decision that various Office Actions were vacated during prosecution

The Decision states on page 2 that "Although the Office does not agree that the January 29, 2009 Office action was 'vacated,' the Office does agree that the 12-day reduction was improper." However, the Petition Decision dated October 8, 2009 was signed by Director Yucel, who did not dispute any of the factual findings outlined in the Petition Decision. Thus, Director Yucel acquiesced to the undisputed factual statements made in the Petition Decision. The Petitions Director has neither pointed to the MPEP nor one of its internal procedures, or otherwise reasoned or provided evidence, to support its finding that Director Yucel did not acquiesce to the undisputed factual statements that the January 29, 2009 Office Action was vacated. Further, there is no evidence that Director Yucel did not acquiesce to all of the undisputed factual statements made in the Petition Decision, including the statements that the June 23, 2009 and December 16, 2008 Office Actions were vacated.

Thus, the Office's finding that Director Yucel did not vacate any Office Actions (except for the August 13, 2009 Office Action) as indicated in the Decision is unlawful as lacking substantial evidence and must be set aside in accordance with the APA and the Supreme Court decision in Zurko.

- e) The Office has not established that only Group Directors have authority to vacate Office Actions

The Decision states on page 2 that "Group Directors in Technology Centers have the authority to vacate Office actions." However, the Office has not pointed to the MPEP or one of its internal procedures and has provided no evidence, and certainly no "substantial evidence," to support this reasoning. The Applicants, after diligent research and review of the MPEP, have found no basis for this finding. Applicants respectfully request that the Office provide a factual basis for this finding. Otherwise, this finding is unlawful as lacking substantial evidence and must be set aside in accordance with the APA and the Supreme Court decision in Zurko.

- f) The Restriction Requirement mailed 3/6/08 should be vacated

As outline above in detail, it is undisputed that the original Restriction Requirement dated October 8, 2008 was replete with errors and in violation of MPEP § 814.

It is undisputed that the Applicants elected Group VIII (Group 8) in the response filed March 19, 2008. It is undisputed that the Decision on Petition dated October 8, 2009, page 1, signed by Director Yucel, confirmed that such an election was made. It is undisputed that the Examiner acknowledged Applicants' election of Group VIII (that is, Group 8), in the Office Action dated June 23, 2008, page 2.

However, the prosecution history was unclear as to which group was examined because the Examiner interchangeably and inconsistently referenced both Groups VIII and XIII in various Office Actions as described above.

In addition, it is undisputed that the original Restriction Requirement dated March 6, 2008 did not comply with MPEP § 814 that requires that "the restriction requirement to provide a clear demarcation between restricted invention so that it can be determined whether the inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double-patenting rejections under 35 U.S.C. 121."

In addition, it is undisputed that in the Petition Decision, the pending claims were "considered for unity of invention *anew* in this decision (emphasis added)." See Petition Decision, page 5. In the Petition Decision, Director Yucel acknowledged "the extensive delays in initiating prosecution on the merits in this application" (page 7). Thus, the Petition Decision suggests the strong intent to render the original Restriction Requirement dated March 6, 2008 void *ab initio*.

Thus, the finding that the original Restriction Requirement was not vacated is unlawful as arbitrary or capricious in view of the Petitions Director's disregard for MPEP § 814. Further, the Petitions Director has provided no evidence as to why it would be proper to act contrary to MPEP § 814. Thus, this finding in particular must be set aside in accordance with the APA and the Supreme Courts' decision in Zurko.

Conclusion

It is undisputed, and the Office acknowledged on at least two occasions, that the Office was responsible for significant errors and delays throughout prosecution of the present application. In contrast, the Applicants have been extremely diligent in advancing prosecution. The Applicants have swiftly filed Responses to Office Actions: one was filed in two weeks of the mailing date of the Office Action and the other within 10 days. Thus, it is not only lawful, but also fair, to reverse the Decision on Application for Patent Term Adjustment and correct the PTA in accordance with the Request for Reconsideration of Patent Term Adjustment. Applicants hereby request that the Office correct the calculation of PTA as of the mailing date of the Notice of Allowance to reflect **864 days**.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 6, 2010

By: /Carolyn Favorito/

Carolyn Favorito
Registration No. 39,183
Attorney of Record
Customer No. 20,995
949-721-2811

9715727
092210